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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/574,946 | 05/19/2000 | Christine K. Shewmaker | ristine K. Shewmaker CGNE.099.00USRe 9904 EXAMINER | |
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| ARNOLD & PORTER LLP | | | FOX, DAVID T | |
| ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206 | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |
| | | | DATE MAILED: 03/11/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|------------------------------------|--|--|--|--|
| Office Action Summer | 09/574,946 | SHEWMAKER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | David T. Fox | 1638 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 13 A | ugust 2003 and 12 December 20 | 03. | | | | |
| | action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-29,81-133 and 136-138</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-29,81-133 and 136-138</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list | * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
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| | | | | | | |
| Attachment(s) | | (270, 440) | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) 🔀 Interview Summary Paper No(s)/Mail Da | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) Notice of Informal F | Patent Application (PTO-152) | | | | |
| Paper No(s)/Mail Date | 6) Other: | | | | | |
| U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office Ac | tion Summary | Part of Paper No./Mail Date 021304 | | | | |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 August 2003 has been entered.

Applicants' properly executed Reissue Declaration of 12 December 2003 is acknowledged.

The application should be reviewed for errors. Errors appear, for example, in claim 81, line 5, where ---gene--- should be inserted after the second recitation of "a"; and in claim 108, last line, where ---initiation region--- should be inserted after "transcriptional".

The amendments of 13 August 2003 have overcome the rejection under 35 USC 251 for cancelled claims 65-80 and 134-135; the outstanding rejections under 35 USC 112, second paragraph; the new matter rejection of claims 129-130 and 138; and the art rejections under 35 USC 102 and 103, except as indicated below. Claims 31-32, 34-80 and 134-135 have been cancelled by the amendment of 13 August 2003. Claims 30 and 33 have been previously cancelled. Claims 1-29, 81-133 and 136-138 are pending and have been examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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The Assignee's offer of 21 December 2000 to surrender the original patent, as reiterated on page 16 of the amendment of 25 November 2002, is acknowledged.

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed.

See 37 CFR 1.178.

Claims 19-29, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States,* 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application, as stated on pages 3-7 in the Office action of 27 September 2001 for claims 19-44 and 62-130.

Applicant's arguments filed 13 August 2003 on pages 9-11 have been fully considered but they are not persuasive. Applicants urge that the recapture rejection is improper, since the instant claims are drawn to *embryonic* seed-specific promoters,

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DNA constructs containing them, and methods for their use to transform plants; or since instant claim 133 is drawn to a method of altering the phenotype of dicotyledonous plant tissue at a specific stage of plant growth; wherein said claims are narrower than those presented in the parent application Serial No. 08/105,852 upon which the instant reissue application is based.

Instant claims 19-29, 81-130, and 136-138 are drawn to DNA constructs comprising embryonic seed-preferred or embryonic seed-specific promoters, plants transformed therewith, and methods for selectively expressing genes of interest in embryonic seed tissue. The Examiner maintains that claims of such scope were in fact presented in the parent application. See claims 107-108 dependent upon claims 22 or 70. as presented in the amendment of 23 October 1995 in the parent application. Claims 22 and 70 are method claims drawn to plant transformation with seed-specific promoters for obtaining a plant with a regulatable and/or altered phenotype in a specific plant part. Claims 107-108 specify that the seed-specific promoters are "transcribed during seed embryogenesis", equivalent to the instantly claimed embryonic seedpreferred promoters and methods for their use to obtain plants with altered phenotypes in embryonic seed tissue.

However, claims 22, 70, 107 and 108 in the parent application were rejected under 35 USC 103 in the Office action of 29 August 1996 (see pages 4-6 of that action), and were subsequently cancelled by the amendment of 02 January 1997, resulting in allowance of the remaining claims, all of which were drawn to fruit-specific promoters.

See In re Clement, 45 USPQ2d 1161, (Fed. Cir. 1997) at page 1165:

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(3) if the reissue claim is broader in some aspects, but narrower in others, then (a) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection [emphasis added], but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim.

Instant claim 133 is drawn to a method for altering the phenotype of a dicotyledonous plant via growing a dicotyledonous plant which has been transformed with a DNA constructs comprising a promoter which is preferentially expressed at a particular developmental stage of plant growth, which encompasses seed embryo development. Claim 101 of the amendment filed 11 April 1995 in the parent application is drawn to a plant cell having an altered phenotype as a result of the introduction of a promoter which is preferentially expressed at a particular developmental stage of plant growth. This claim was rejected under 35 USC 112, first paragraph, on pages 3-6 of the Office action of 21 June 1995. This claim was cancelled by the amendment of 23 October 1995. That amendment also presented claims broadly drawn to any seed-specific promoter and methods of its use, as stated above, which claims were encompassed by the subject matter of claim 101, and which claims were rejected under 35 USC 103 in the Office action of 29 August 1996, as stated above. In response to this art rejection, all claims not drawn to fruit-specific promoters were cancelled by the subsequent amendment.

Thus, subject matter corresponding to instant claim 133 was cancelled in the parent application in response to a rejection under 35 USC 112, first paragraph and a prior art rejection. The limitation of "dicotyledonous" was not germane to the enablement or prior art rejections in the parent application. See *Clement* above.

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Thus, Applicants are improperly attempting to recapture subject matter which was surrendered during the prosecution of the parent application by cancellation of claims corresponding to the instant claims, which had been rejected under 35 USC 112 and 103. The putative differences in scope between the instant and parent claims are not germane to the rejections applied to the parent claims. Accordingly, *Clement* supports the Examiner's position.

Claims 131-132 are no longer subjected to the above rejection. These claims are drawn to dicotyledonous plant cells comprising DNA constructs comprising light-regulatable or chloroplast-containing-tissue-preferred promoters. It is now considered that claims corresponding to this subject matter in the original patent application were not cancelled in response to art rejections or any other type of rejection. The Office action of 29 August 1996 in parent application Serial No. 08/105,852 did not reject claims 26 or 69, presented in the amendment of 23 October 1995, to any prior art or enablement rejection. Claim 26 is of similar scope to instant claim 131 with respect to the DNA construct. These claims were subsequently cancelled in the amendment of 02 January 1997, but were not subjected to any rejection other than an obviousness-type double patenting rejection. See *Clement* cited above.

The effective filing date for claims 19-29, 81-130, 133 and 136-138, insofar as they are drawn to seed-specific promoters and their use, is 31 July 1986, the filing date of parent application Serial No. 06/891,529 which was the earliest parent to teach such a promoter.

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Claims 19-29, 81-130, 133 and 136-138 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,420,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a seed-specific promoter and plant cells containing them, as claimed in the patent; to obtain the DNA constructs containing a seed-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the instant application; as stated on page 8 in the office action of 27 September 2001 for claims 19-29 and 62-130.

Claims 97-100, 113-128 and 131-133 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,750,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a chloroplast-containing-tissue-specific promoter and methods for their use to obtain plant cells containing them, as claimed in the patent; to obtain the DNA constructs containing a chloroplast-containing-tissue-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the instant application; as stated on pages 8-9 in the Office action of 27 September 2001 for claims 19-44 and 62-130.

Claims 1-18, 97-100, 113-128 and 133 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1-14 of U.S. Patent No. 4,943,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a fruit-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the patent; to obtain the DNA constructs containing a fruit-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the instant application; as stated on page 9 in the Office action of 27 September 2001 for claims 1-29 and 45-130.

Claims 19-29, 81-130, 133 and 136-138 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-47 and 50-54 of copending Application No. 09/782,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the methods of obtaining seed-specific transcription or phenotypic alteration by plant transformation with seed-specific promoters including seed embryogenesis-specific promoters, as claimed in the copending application; to obtain the instantly claimed DNA constructs containing an embryonic seed-specific promoter and methods for their use to obtain transformed plant cells and plants containing them.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Applicants' intent on page 11 of the amendment of 13 August 2003 to file

Terminal Disclaimers is noted. The double patenting rejections will be maintained until receipt of properly executed Terminal Disclaimers.

Claims 19-29, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the use of *Brassica*-derived seed-specific promoters for seed-specific gene expression, transcription, or phenotypic alteration; or for light-inducible/chloroplast-containing-tissue-specific or fruit-specific promoters and methods for their use; does not reasonably provide enablement for claims broadly drawn to the use of any promoter or any regulatory sequence from any plant source to effect seed-specific gene expression, transcription or phenotypic alteration; or any promoter which would effect any type of plant developmental stage-specific expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 11-13 in the Office action of 27 September 2001 for claims 19-29 and 62-130.

Applicant's arguments filed 13 August 2003 have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection is improper, given the disclosure in the specification and the prior art of various seed-specific promoters from various plant species, and the disclosure in the specification of how to isolate other seed-specific promoters. Applicants also cite *Engel Industries, Inc. v. Lockformer Co.* and *The Johns Hopkins University v. CellPro, Inc.* to support their position.

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The Examiner maintains that the excerpted portions of the specification are insufficient to enable the broadly claimed invention. Columns 17-25 demonstrate the isolation of seed-specific promoters from Brassica only. A cDNA clone encoding acyl carrier protein from spinach did not include the promoter region. Furthermore, isolation of the cruciferin gene or its associated promoter was not demonstrated. The paragraph bridging columns 7 and 8 merely provides a wish list of other genes and plants from which to isolate promoters, and the paragraph bridging columns 30 and 31 only provides brief suggestions of method steps which could be utilized. As taught by *Bayer v. Housey*, Fed. Cir. 2003, Appeal No. 02-1598, "processes of identification and generation of data are not steps in the manufacture of a final ... product".

Regarding the state of the prior art, please see Genentech cited previously.

Regarding *Engel*, the Examiner notes that the Decision focused on best mode requirements, and only briefly mentioned enablement by distinguishing it from best mode. The Court in *Engel* also noted that the district court did not demonstrate a lack of enablement, so that a similar finding could not be reached or upheld by the Federal Court. See 20 USPQ2d 1300 at 1304. Thus, *Engel* cannot be relied upon for any substantive teaching about the requirements for enablement, and certainly does not refute the requirements set forth in *In re Wands*, which requirements were relied upon by the Examiner in the first Office action.

Regarding *Johns Hopkins*, different fact patterns were involved. In that case,
Patentee claimed antibodies *per se*, and the infringer unsuccessfully argued that claims
to the antibodies were not enabled since not all of the disclosed methods for making

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them would work. The Federal Court found that since the specification taught at least one operable way to make the antibodies, claims to the antibodies themselves were enabled. The breadth of the patent claims regarding the type of antibody was not at issue. In the instant application, it is the breadth claims directed to the products, i.e. the seed-specific promoters, and methods of using them, that is at issue. Applicants do not propose multiple methods to obtain a single seed-specific promoter. Instead, Applicants provide only one method for obtaining seed-specific promoters from one plant genus, while claiming any seed-specific promoter from any plant genus, and methods of their use. Furthermore, the Court in *Hopkins* upheld the enablement of the patent claims because the infringer improperly relied upon the experiences of unskilled artisans, rather than ordinarily skilled artisans, to demonstrate unpredictability (see 47 USPQ2d 1705 at page 1718).

Claims 19-29, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 13-14 of the Office action of 27 September 2001 for claims 19-29 and 62-130.

Applicants urge that the written description rejection is improper, given the disclosure in the specification and the prior art of various seed-specific promoters from various plant species, the disclosure in the specification of how to isolate other seed-specific promoters, and the lack of a requirement that "every nuance of the claims is

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explicitly described in the specification" if "a person of ordinary skill in the art" would have otherwise "understood the inventor to have been in possession of the claimed invention at the time of filing", as taught by *In re Alton* (Response, page 14, top paragraph).

The Examiner maintains that neither the specification nor the prior art provide any guidance regarding the identification of any structural features, i.e. conserved DNA sequences, common to all seed-specific promoters, as required by MPEP 2163, *Lilly*, and the Written Description Guidelines, all cited previously. Thus, inadequate written description of the broadly claimed genus, which encompasses all seed-specific promoters from all unrelated plant genera and species, has been provided by Applicants' disclosure of the isolation of three seed-specific promoters from *Brassica* genes. Similarly, no structural features have been disclosed which are common to all promoters which preferentially express at any "specific stage of plant growth" in any tissue or organ, as claimed in claim 133. See also *Bayer v. Housey* cited above.

Regarding *Alton*, the Examiner maintains that different fact patterns were involved, and that *Alton* is not conclusive. In that case, Applicant narrowly claimed a particular gamma interferon analog with deletions of particular amino acid residues. The Court found that the Examiner failed to adequately address Appellants' submission of a declaration demonstrating that Appellants were in possession of the particularly claimed analog. The Court then remanded the case to the Patent Board of Appeals and Interferences for further evaluation of the declaration (see 37 USPQ2d 1578 at 1582 and 1584). Such a remand demonstrates that the Court did not yet recognize

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Appellants to have been in possession of the claimed invention, and did not believe that a person of ordinary skill would have understood this to be the case.

In the instant case, Applicants are broadly claiming any and all seed-specific promoters from any and all plant genera and species. Applicants have not provided any declaration or other evidence that they were in fact in possession of seed-specific promoters from any plant genus other than *Brassica* at the time of filing.

Claims 22, 24-27, 97-99, 101-102, 105, 107-109, 113-115, 117-118, 121, 123-125, 133 and 137 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al (U.S. Patent 5,504,200 effectively filed 15 April 1983).

The claims are drawn to a DNA construct comprising a seed embryo-specific promoter and a DNA sequence of interest from a gene which is native to a plant host (claim 22) or which is not the native coding sequence from a gene native to a plant host (claims 97-98, 101, 105, 108, 113-114, 117, 121, 124, 133 and 137, and dependents). The above claims are also drawn to methods of using the DNA constructs to alter phenotypes in seeds of transformed plants including dicotyledonous plants, wherein the DNA sequence of interest may confer "increased capability of protein storage" and "improved nutrient source".

Hall et al teach DNA constructs comprising the phaseolin promoter, which is inherently seed embryo-specific, as admitted by Applicants on page 12 of the response of 13 August 2003, middle paragraph. Hall et al explicitly teach that phaseolin gene expression is limited to the cotyledons, i.e portions of the developing embryo, of seed tissue (see, e.g., column 9, line 55 through column 10, line 16). Hall et al also teach the

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ligation of the phaseolin promoter with a phaseolin coding sequence, wherein said phaseolin coding sequence is native to a bean plant, and wherein phaseolin is a leguminous seed storage protein. Hall et al also teach DNA constructs comprising intron-less cDNA versions of the phaseolin coding sequence, wherein said cDNA versions are not native to the phaseolin promoter in the plant genome. Hall et al also teach the use of the intronless phaseolin coding sequence with the phaseolin promoter. and teach plant transformation with the DNA constructs, including transformation of the dicotyledonous plant tobacco; wherein the process of plant transformation taught by Hall et al inherently results in seed embryo-specific expression of the phaseolin coding sequence, which alters the seed phenotype by conferring improved nutritional source and increased protein storage to the embryonic cotyledons of the transformed tobacco seeds. See Hall et al, Figures 18 and 22; column 9, line 55 through column 10, line 16; column 10, line 65 through column 11, line1; column 16, line 36 through column 17, line 32; column 19, line 30 through column 20, line 14; column 23, line 11 through column 24, line 5; column 27, line 64 through column 29, line 66.

The patent teaches all of the individual elements (DNA constructs comprising either the native phaseolin gene or an intron-less phaseolin gene ligated to the phaseolin promoter; heterologous antibiotic resistance genes ligated to plant-expressible promoters; plants transformed with DNA constructs comprising the phaseolin promoter ligated to the native phaseolin gene and a heterologous antibiotic resistance gene ligated to a plant-expressible promoter), and suggests their

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combination, thus providing a constructive reduction to practice, as taught by *In re Sivaramakrishnan*, 213 USPQ 441 (CCPA 1982) at page 442, penultimate paragraph.

See also Integra Life Sciences I Ltd. v. Merck KGaA, 50 USPQ2d 1846 (DC SCalif, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products.

Claims 19-27, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al., as stated on pages 19-21 of the Office action of 27 September 2001 for claims 19-27 and 62-130.

Applicant's arguments filed 13 August 2003 have been fully considered but they are not persuasive.

Applicants urge that the art rejections involving Sengupta-Gopalan et al are improper, given the support in the earliest-filed parent application for seed-specific promoters, which application predates Sengupta-Gopalan et al. The Examiner maintains that the mere recitation in the parent application of a *light-inducible* promoter does not provide any enablement for isolated *seed-specific* promoters or methods of their use for plant transformation. The parent application does not demonstrate the identification or isolation of any seed-specific gene or its promoter, or plant transformation therewith. Thus, the claimed subject matter was not adequately

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disclosed under 35 USC 112, first paragraph, in the parent application, so that Applicants are not entitled to the benefit of the earlier filing date.

Applicants urge that the art rejection over Hall et al taken with Sengupta-Gopalan et al is improper, given the failure of either reference taken by itself to teach or suggest the use of a seed-specific promoter ligated to a DNA sequence of interest which is other than the native coding sequence of the gene from which the seed-specific promoter was isolated, including a DNA sequence encoding a product which modulates the expression of endogenous products.

The Examiner maintains that the references *taken together* provide the suggestion to combine their teachings and obtain plant transformation with a DNA construct comprising the seed-specific phaseolin promoter of Hall et al or Sengupta-Gopalan et al ligated to a heterologous coding sequence such as the antibiotic resistance marker gene also taught by Hall et al, as stated in the last Office action. Hall et al also suggest the introduction of a broad range of genes for the alteration of a variety of traits of interest, and also suggest the introduction of another copy of an endogenous coding sequence into the transformed plant host (see, e.g., column 10, lines 50-56; column 12, lines 36-45).

Finally, it is noted that many of the claims do not specify that the expression of an endogenous gene is modulated. It is also unclear whether Applicants have in fact demonstrated this aspect of the claimed invention.

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See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Claims 28-29 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al. as applied to claims 19-27, 81-130, 133 and 136-138 above, and further in view of Zambryski et al. taken with Pedersen et al., as stated in the Office action of 27 September 2001 on pages 21-22.

Applicant's arguments filed 13 August 2003 have been fully considered but they are not persuasive.

Applicants urge that the art rejection over Hall et al taken with Sengupta-Gopalan et al, further in view of Zambryski et al and Pedersen et al, is improper, since the tertiary and quarternary references do not cure the deficiencies of the primary and secondary references. The Examiner maintains that the primary and secondary references taken together are not deficient, as stated above.

Claims 1-18 remain free of the prior art for the reasons presented in allowed parent application 08/105,852 corresponding to U.S. Patent 5,753,475.

Claims 131-132 remain free of the prior art, given the failure of the prior art to teach or suggest a method for obtaining light-induced heterologous gene expression specifically in chloroplast-containing plant tissue, as stated in allowed related application Serial No. 08/484,941 which issued as U.S. Patent 5,750,385.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 13, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 /63